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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,254

08/01/2003

Douglas G. Evans

150-PDD-02-01-US

4792

7590

01/29/2007

C.R. Bard, Inc.
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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/633,254

Applicant(s)

EVANS ET AL.

Examiner

Julian Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 16-23, 27-38, 42, 46-52 and 117-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 27-38 and 42 is/are allowed.
- 6) ☒ Claim(s) 16-23, 46-52 and 117-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/7/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe or apply the term "rib" as applied in these claims.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 117-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 117, "the flattened portion" lacks antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Matoba et al. (5,689,860). Matoba et al. disclose, at least in figure 1, a connector including an elongated base portion (13 and 17) having first engaging structure (19) at a first end and a second engaging structure (19) at a second end; a first arm (16) pivotally mounted to the elongated base portion and having a third engaging structure (20), the third engaging structure being positioned so that when the first arm pivots toward the elongated base portion, the first and second engaging structures meet and engage; and a second arm (another element 16) pivotally mounted to the elongated base portion and having a fourth engaging structure (21), the fourth engaging structure being positioned so that when the second arm pivots toward the elongated base portion, the second and fourth engaging structures meet and engage; where the first, second, third, and fourth engaging structures comprises an opening (21) or a projection (19), where the elongated base portion and the first and second arms are integrally formed, where the connector comprises what is deemed a "rib" (another element 13) extending from the elongated base portion, where the first and second arms extend from the "rib," where the first and second arms and the "rib" are integrally formed, where the first and second arms include living hinge portions (15), and where the projection (19) includes a flange as claimed. Note: The introductory statement of intended use ("for attachment to at

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least one of an implant member and an introducer needle including a flat spatulated section having an opening") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Matoba et al., which is capable of being used as claimed if one desires to do so.

7. Claims 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Stein et al. (5,774,994). Stein et al. disclose, at least in figures 1-4, a handle including a housing (12) with an elongated portion having an opening (40) in its distal end, an elastically-biased latch portion (14) having a projection (54), an insert (56) having a slot, and a spring (52) pressing against the latch portion, where the housing comprises first and second shell sections (32, 34) mated together. Note: The introductory statement of intended use ("for an introducer needle having a flat spatulated section having an opening") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Stein et al., which is capable of being used as claimed if one desires to do so.

8. Claims 46, 47, and 50-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Bond et al. (6,675,483). Bond et al. disclose, at least in figures 1-6 and in col. 6, line 45 to col. 7, line 7; a handle (12) including a housing with an elongated portion having an opening (80) in its distal end, an elastically-biased latch portion (56) having a projection (54), where the housing comprises first and second shell sections mated together, where the latch portion comprises a latch member (56) having a central pivot (at 65), a curved section, and an end catch section having a projection (54); where the latch portion is an integral part of the housing, and where the handle comprises a

weight (e.g., 102) within the housing. Note: The introductory statement of intended use ("for an introducer needle having a flat spatulated section having an opening") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Bond et al., which is capable of being used as claimed if one desires to do so.

Allowable Subject Matter

9. Claims 1-4, 27-38, and 42 are allowed.
10. Claims 117-119 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a system for supporting a female urethra having an introducer needle with a flattened portion and an opening, a handle having a latch, an implant member, and a connector joining the implant member to the flattened portion of the needle; an introducer needle with, inter alia, first and second flat spatulated sections and a flared section connecting the first flat spatulated section to a central portion; an introducer needle with, inter alia, a tubular body with a lumen, a rod, needle tip movably disposed in the lumen, and a pushbutton connected to the rod; an introducer needle and a handle for the needle, and where the needle has a body portion, a flared section, and flat spatulated section with a "T"-shaped opening.

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As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

12. The Examiner's indication of allowable subject matter in claims 16-23 and 46-52 is withdrawn in view of new grounds of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. De Marre (3,126,600), Fusillo (5,473,796), and Boisvert (5,655,270) teach connectors, while McBride (4,409,866) and Chien (6,336,731) teach handles.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

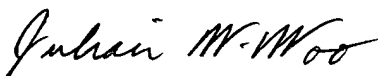
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Julian W. Woo". The signature is fluid and cursive, with the first name "Julian" being more prominent than the last name "Woo".

Julian W. Woo
Primary Examiner

January 10, 2007